UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: **Repeat Section 18 - Specific Exemption** for Soil Drench Use of Clothianidin on Immature Citrus Trees to Manage the Transmission of Huanglongbing Disease Vectored by the Asian Citrus Psyllid in Florida (22FL01)

FROM: Marietta Echeverria, Acting Director
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TO: Ed Messina Esq., Director
Office of Pesticide Programs

I. APPLICANT REQUEST

Applicant: Florida Department of Agriculture and Consumer Services

Chemical: Clothianidin (CAS No. 210880-92-5)

Product: Belay® Insecticide (EPA Reg. No. 59639-150) manufactured by Valent U.S.A. LLC

Site: Immature (3-5 years of age) Citrus Trees

Pest: Asian Citrus Psyllid, a vector for Huanglongbing Disease

Rate: Belay Insecticide® may be applied via soil drench at a single maximum application rate of 0.2 lb. a.i./A (12.0 fl. oz. per acre) to immature citrus trees (3 to 5 years old), with a maximum of 0.4 lb. a.i./A (24.0 fl. oz. per acre) per 12-month period regardless of tree size, tree count per acre or application method.

Restrictions: Do not apply more than 2 applications per tree per 12-month period. Allow a minimum of 4 months between applications. Do not apply product from November 1 through the end of the following bloom period. Applications cannot be made to trees in full bloom to reduce exposure to pollinators. A minimum 1-day pre-harvest interval (PHI) and a 12-hour restricted entry interval (REI) must be observed.

Acreage: A maximum of 125,376 acres of young citrus trees may be treated under the exemption except between November 1 and the end of winter/spring bloom.

Use Season: October 15, 2022 through October 15, 2023

II. BACKGROUND

EPA granted the Florida Department of Agriculture and Consumer Services (FDACS) a specific exemption in 2014 and determined that the emergency condition was recertifiable due to the introduction of a new pest and pathogen, and because the infestation was expected to continue in the foreseeable future. Since that time, the emergency exemption has been approved by EPA annually, and the last authorization was granted on December 23, 2020. EPA received a ninth emergency exemption reauthorization request from FDACS on December 3, 2021 for the identical use pattern. EPA published a notice of receipt in the Federal Register on February 1, 2022 (87 FR 5475) FRL-9458-01). EPA received four comments. The United States Department of Agriculture (USDA) commented supporting authorization of the requested use of clothianidin. There were 3 comments that opposed emergency use of clothianidin two were submitted from private citizens and the Center for Biological Diversity. EPA has responded to the commenters in detail in a separate response to comment document that is available for view on [HYPERLINK "http://www.regulations.gov"], identified by docket identification number (EPA-HQ-OPP-2021-0952).

In reviewing the application and public comments, EPA determined the State's application required additional information and did not meet the conditions for recertification because the application did not include information about the alternative active ingredients (cyantraniliprole and flupyradifurone) registered to manage ACP since 2014. After discussion with EPA, FDACS submitted additional information on potential alternative pesticides that have been registered since 2014. FDACS also provided information to support the analysis of risks to pollinators and threatened and endangered species. This information was submitted to EPA on May 19, and July 22, 2022.

According to FDACS, citrus growers have an urgent and critical need for clothianidin use in citrus. Clothianidin is one of three neonicotinoid insecticides commonly used on newly planted/young citrus trees to delay Huanglongbing (HLB) infection. There are many insecticides that can be used for the management of the vector, Asian citrus psyllid (ACP). However, only imidacloprid, clothianidin, and thiamethoxam have been proven to interfere with the feeding interaction between ACP and the host plant, citrus, and thereby reduce the likelihood of pathogen transmission. By delaying infection by the pathogen, trees can develop viable roots and potentially survive to bearing age and develop into productive trees.

FDACS contends that HLB is considered the most serious disease of citrus worldwide and since its discovery in Florida, it has spread rapidly and extensively throughout all commercial citrus production areas in the state. Citrus and citrus acreages are being decimated by this disease. Based on the most recent National Agricultural Statistics Service (NASS) Citrus Summary report issued March 2022, there are approximately 369,300 bearing acres in commercial plantings for all varieties of citrus in the state of Florida, which compares to a total of 641,400 bearing acres of citrus in the state when HLB was first discovered. As growers plant new citrus trees to try to stop further acreage declines, these newly planted/young citrus trees need a full 12-months of protection from ACP feeding and subsequent HLB infection. Applications of imidacloprid and thiamethoxam work to provide nine months of protection to these young trees. Access to clothianidin soil drench treatment is necessary in combination with the other two neonicotinoid insecticides, to provide full 12-month protection. The impacts from clothianidin application continue to be significant, with more than 37,000 of young citrus trees receiving a clothianidin soil drench ACP antifeeding treatment during the previous citrus production cycle.

Progress Toward Registration: The Section 3 registration application submitted by Valent in 2014 and the associated tolerance petition submitted by IR-4 were withdrawn in response to the 2015 Agency policy which indicated that new outdoor uses for neonicotinoids were unlikely to be registered until the completion of neonicotinoid registration review. In this policy, EPA acknowledged that a pest management need could arise during the interim period that would support the issuance of an emergency exemption request under FIFRA Section 18. EPA determined that the emergency scenario in Florida supports authorization of clothianidin for use on citrus to control ACP. Valent and the IR-4 program continue to support existing registrations of clothianidin and have been actively involved in the registration review process, commenting on the proposed interim decision for the neonicotinoids, and submitting data and comment on the protection of pollinators. EPA has given due consideration that the registrant has made reasonable progress toward registration.

Reregistration Review: The Agency generally reviews registered pesticides on 15-year cycles to determine whether the chemical continues to meet the FIFRA standards for registration. Clothianidin is currently in the first round of registration review. The amended Proposed Decision date is expected March 30, 2023 and the tentative Interim Decision Signature date is in March 2024.

III. EPA EVALUATIONS

BIOLOGICAL AND ECONOMIC ANALYSIS

In 2014, the Biological and Economic Analysis Division (BEAD) reviewed Florida's emergency exemption request and determined that there are no effective available alternatives for season long protection of 3- to 5-year-old citrus trees in Florida and that infestations of Asian citrus psyllid (ACP) are likely to result in yield/quality losses in excess of 20%, even with the use of currently registered insecticides. BEAD concluded that the emergency condition was urgent and non-routine and that citrus growers in Florida were likely to experience significant economic losses due to ACP transmission of Huanglongbing (HLB). This year, BEAD reviewed the reauthorization request for use of clothianidin on citrus and determined the emergency situation meets the urgent and non-routine standard under FIFRA. In addition, EPA determined that there are insufficient effective registered pesticides or combinations of pesticides to provide season-long protection of 3–5-year-old citrus trees and reliably reduce ACP populations to levels that prevent HLB transmission. EPA concluded in its review that newer registered pesticides do not substantially change the pest control options for citrus growers and that yield loss for infected young citrus trees is 100% without season-long management of ACP to prevent the spread of HLB.

Biological Analysis:

The Asian citrus psyllid, *Diaphorina citri*, is a tiny mottled brown insect, about the size of an aphid, which poses a serious threat to citrus trees. The psyllid feeds on all varieties of citrus (e.g., oranges, grapefruit, lemons, and mandarins) and damages citrus directly by feeding on new leaf growth (aka flush). Feeding on the new leaf growth twists and curls young leaves and kills or burns back new shoots. The degree of damage to young citrus trees is substantial. The insect is a vector of the bacterium *Candidatus Liberibacter asiaticus*, associated with the fatal citrus disease Huanglongbing, also called citrus greening disease. The psyllid takes the bacteria into its body when it feeds on bacteria-infected plants. The disease spreads when a bacteria-carrying psyllid flies to a healthy plant and injects bacteria into it as it feeds. The only way to protect trees is to prevent the spread of the HLB pathogen by

controlling psyllid populations and removing and destroying any infected trees. Symptoms of HLB infection can take up to several years to present themselves in infected trees. HLB negatively affects yield, fruit size and quality, as well as tree mortality. HLB can kill a citrus tree within five years. In Florida, citrus growers estimate that approximately 90% of acreage is infected with HLB with a corresponding 41% average yield loss (Singerman and Useche 2016).

Newer Pesticides:

In its review of the newer systemically active insecticides registered in the last five years, EPA determined that afidopyropen, cyantraniliprole, flupyradifurone, and sulfoxaflor were limited in their use protecting young citrus trees under the conditions of this emergency pest situation. In addition, EPA concluded the following limitations applied to the newer registered pesticides:

- Lack of field scale data for afidopyropen efficacy in terms of protecting young trees from HLB transmission.
- Sulfoxaflor and afidopyropen are not recommended by extension for ACP control via soil drench and do not currently appear to fulfill the gap in soil drench applications for ACP.
- Flupyradifurone is not recommended for soil applications against ACP and extension recommends retaining two foliar applications of flupyradifurone rather than applying one soil drench application. The duration of activity on ACP for these active ingredients and use patterns does not appear to sufficiently fill the gap in soil applications needed for ACP in young citrus.
- Application limits for some of the newer AIs (e.g., one soil application per year or two foliar applications for cyantraniliprole), along with the need to rotate this and other chemistries throughout the season to reduce and avoid neonicotinoid resistance. When mature and young trees are on the same acre, growers who use cyantraniliprole for soil drench treatment of young trees would have to find a way to treat their more mature trees with a foliar application (to manage neonicotinoid resistance) without violating the one application annual limit per acre, because foliar applications are applied with airblast sprayers that spread insecticide across all trees.
- Recent reductions in the effectiveness of cyantraniliprole due to incipient resistance in ACP populations.

According to FDACS, clothianidin is a critical neonicotinoid tool in reducing the transmission of the pathogen. The other registered neonicotinoids, imidacloprid and thiamethoxam do not provide season-long protection because of limits on the number of soil drench applications Florida citrus growers can make in a year and clothianidin closes the gap in the year-long spray schedule. Soil application of systemic insecticides is the currently recommended approach to protect young citrus trees because they have the vigor to absorb enough dosage to provide long-lasting efficacy and feeding disruption. Typically, growers can make two applications of imidacloprid and one application of thiamethoxam which provide 9 months of control, but protection is necessary for the full year. Emergency use of clothianidin fills the three-month gap in application for trees 3-5 years old and affords citrus growers year-round protection using plant-systemic insecticides.

Based on these factors, BEAD concludes that the newer AIs do not fill the gaps in protection for year-round control of ACP when used in combination with existing tools. Growers in Florida face an urgent and non-routine pest control situation and they must protect both immature citrus trees along with mature ones. Without season-long management of ACP to prevent the spread of HLB, the potential future yield loss for infected young bearing trees is 100% because the disease can cause the complete loss of the tree before it reaches market maturity.

Economic Analysis:

[SEQ CHAPTER \h \r 1][SEQ CHAPTER \h \r 1]FDACS did not provide per acres yield loss data but reported information on state-level impacts of ACP and HLB on Florida citrus with an emphasis on orange production. The state reported that orange production in Florida has been steadily declining over the history of this pest and based on (USDA NASS 2006) data, Florida produced 230 million boxes of oranges during the 2001-2002 season. In the May 2022 forecast, USDA predicted that 40.2 million boxes would be produced in the 2021-2022 season (USDA NAAS 2022). In addition, sugar levels in citrus groves infected with HLB have declined and do not meet the Brix standard, currently 10.5%, which is the Food and Drug Administration required level of sugar in pasteurized, not-from concentrate orange juice. Further, the average Brix value in Florida oranges is 9.62 (USDA NASS 2022) and processing plants have been importing oranges from other countries to supplement the Florida harvest and meet the standard.

BEAD concludes that without season-long management of ACP to prevent the spread of HLB, the potential yield loss for infected immature bearing citrus trees is 100% because the disease causes the complete loss of the tree before it reaches market maturity. If the tree survives to maturity, infestations of ACP and subsequent HLB infection are likely to result in yield/quality losses more than 20%, even with the use of currently registered insecticides. More details on the biological and economic analysis are discussed in the document, *Review of a Repeat Emergency Exemption Request from Florida for the Use of Clothianidin to Control the Asian Citrus Psyllid on Immature Citrus (22FL01; DP#465496)*, which is available in the docket for this action: (https://www.regulations.gov//EPA-HQ-OPP-2021-0952).

HEALTH EFFECTS RISK ASSESSMENT

In 2014, EPA conducted a review of the proposed emergency use of clothianidin as a soil drench application on immature citrus trees in Florida. EPA concluded that there are no dietary, occupational, or aggregate (food, water, residential) exposures or risk estimates of concern. In addition, a time-limited tolerance in connection with this action is established in 40 CFR §180.586(b) for fruit, citrus group 10-10. EPA determined this level is adequate to protect public health. These risk conclusions remain unchanged and support the current Section 18 emergency reauthorization request from FDACS. EPA relies on the results from the 2014 risk assessment, *Clothianidin - Aggregate Human Health Risk Assessment for the Section 18 Use on Immature Citrus Trees in FL (14FL03)*, which can be found in the docket for this action: ([HYPERLINK "http://www.regulations.gov"]/EPA-HQ-OPP-2014-0253).

ENVIRONMENTAL FATE AND EFFECTS ASSESSMENT

In 2014, the Environmental Fate and Effects Division (EFED) reviewed the proposed emergency

exemption request for use of soil applications of clothianidin to control ACP transmission of HLB in citrus trees and concluded that the maximum proposed single application rate on citrus (bearing and non-bearing trees less than five years old) is similar to the maximum single application rate of other currently registered soil application rates on brassica, cucurbit and fruiting and leafy vegetables. Based on estimated maximum application rates, exposure levels, and available effects data, clothianidin use on citrus in Florida may lead to listed and non-listed species effects on freshwater and estuarine/marine invertebrates, birds, mammals, and beneficial terrestrial invertebrates from acute and chronic exposures. However, EPA determined in 2014 that it was unlikely there would be increased exposure or new species impacted from the proposed section 18 use on citrus than currently may exist from already registered uses of clothianidin. The risk conclusions from the 2014 ecological risk assessment, *EFED Response to Florida's Section 18 Emergency Exemption for the Use of Clothianidin to Control Asian Citrus Psyllid Transmission of Huanglongbing Disease to Bearing and Non-bearing Citrus Trees,* can be found in the docket for this action: ([HYPERLINK "https://www.regulations.gov" \h]/EPA-HQ-OPP-2021-0952).

EPA determined that the emergency exemption action from FDACS for the use of clothianidin on citrus is one to which EPA's obligations under Endangered Species Act section 7 apply. In its evaluation of the Section 18, EPA completed effects determinations for federally listed threatened and endangered species and their designated critical habitats for the use of clothianidin soil drench applications on young citrus trees within the state to control ACP. EPA determined that a total of 56 listed species and three critical habitats overlap with the proposed action area. EPA made No Effect (NE) determinations for six of the listed species that are within the proposed action area. Further, EPA made May Affect (MA) but Not Likely to Adversely Affect (NLAA) determinations for the other 50 listed species and the three designated critical habitats within the proposed action area. All species and critical habitats for which EPA made NLAA determinations are under the authority of the U.S. Fish and Wildlife Service (FWS). Based on these conclusions, EPA informally consulted with FWS on August 25, 2022 regarding its determinations on those species and critical habitats with NLAA determinations and on September 9, 2022 received a letter of concurrence from FWS.

In addition, EPA's BE considered risks to pollinators and potential effects to terrestrial invertebrates feeding on pollen and nectar (which likely represents pollinators such as native bees and butterflies) from treated blossoms. EPA concluded that mortality to pollinators is not expected from acute exposures to clothianidin. EPA identified potential risk to pollinators from chronic exposures. If terrestrial invertebrates feed on the same clothianidin-treated orchards for 6 days or longer (chronic exposure), then there may be an adverse effect; however, it is uncertain if terrestrial invertebrates will feed on clothianidin-treated sites frequently enough to elicit an effect because not all citrus acres will be treated (up to 9.3% is expected) and pollinators generally visit a variety of blooming plants (not just citrus). To minimize exposure to pollinators, Florida citrus growers must observe the following application statement: "Do not apply this product until after petal fall." Adherence to the Section 3 and Section 18 use directions and label restrictions to ensure that pollinator exposure is mitigated during application. A targeted residue study indicates that residues in citrus pollen and nectar decline after application. Inclusion of an application restriction on the label between November 1 and the next bloom period (February-March the following year) also helps to reduce exposures to pollinators feeding on treated citrus pollen and nectar. In addition, soil drench applications at the base of the tree minimize off site transport of clothianidin such that spray drift to non-target areas inhabited by pollinators is not of concern.

Based on these conclusions, EPA informally consulted with FWS on August 25, 2022 regarding its determinations on those species and critical habitats with NLAA determinations. For more detailed information on EPA's determinations please see the Agency's assessment, *Biological Evaluation for section 18 request for clothianidin applications to citrus in Florida: Effects Determination for Federally Listed Endangered and Threatened Species and Designated Habitats*, and the FWS informal consultation concurrence letter dated September 9, 2022, which can be found in the docket for this action: ([HYPERLINK "https://www.regulations.gov/EPA-HQ-OPP-2021-0575" \t "_blank"]).

The Registration Division recommends that the Florida Department of Agriculture and Consumer Services be granted a specific exemption for the use of clothianidin on immature citrus trees to manage the transmission of Huanglongbing disease caused by the Asian citrus psyllid. This recommendation is based on the following:

1. BEAD reviewed the clothianidin reauthorization request (identical to the original exemption evaluated in 2014) and evaluated newer active ingredients (AIs) that may have changed the pest management options for control of ACP in young citrus trees. BEAD concluded that an emergency condition still exists because these newer AIs do not substantially change the urgent and non-routine pest condition in Florida. Without season-long management of ACP to prevent the spread of HLB, growers face 100% yield loss for infected young citrus trees.

2. HED reviewed the Section 18 request in 2014 and concluded that the proposed emergency use of clothianidin on citrus would not result in dietary, occupational, or aggregate (food, water, residential) exposures or risk estimates of concern. These risk conclusions remain unchanged and support the current Section 18 reauthorization request for this use. The toxicological, residue chemistry, dietary-exposure, and occupational/residential exposure assessments support the time-limited tolerance established for residues of clothianidin of 0.07 ppm in/on citrus established in 40 CFR §180.586(b) for fruit, citrus group 10-10. EPA determined this level is adequate to protect public health.

3. EFED completed a biological evaluation and informal consultation with FWS for the proposed emergency use of clothianidin as a soil drench application to citrus trees in Florida and determined that potential clothianidin exposures to listed species and taxa upon which they depend may occur on land with treated citrus groves. EPA considers exposures of the treated site to be insignificant based on the fate and chemical properties of clothianidin. Bloom restrictions placed on the label prohibiting applications between November 1 and the end of the following year's bloom is expected to reduce exposures to insect pollinators.

4. There is potential for invertebrate mortality from chronic exposure; however, it is uncertain if terrestrial invertebrates will feed on clothianidin-treated sites frequently enough to elicit an effect because not all citrus acres will be treated, and pollinators generally visit a variety of blooming plants. Moreover, EPA requires the following restriction "Do not apply this product until after petal fall," which, along with adherence to the Section 3 and Section 18 use directions and label restrictions minimize exposure to pollinators. EPA determined that vertebrate animals that consume leaves, pollen and nectar from treated citrus are not affected as exposure concentrations are orders of magnitude below No Observed Adverse Effects Concentrations. Therefore, there are no direct effects to mammals, birds, terrestrial-phase amphibians, or reptiles. EPA concludes that emergency use of clothianidin is not likely to adversely affected 50 listed species and 3 critical habitats.

5. This is the ninth year that emergency use of clothianidin has been requested for control of ACP to manage the transmission of HLB in young citrus trees under section 18 of FIFRA. EPA determined that an urgent and non-routine pest control situation exists for Florida citrus growers and supports reauthorization of clothianidin. Valent and the IR-4 program continue to support existing registrations of clothianidin and have been actively involved in the registration review process, commenting on the proposed interim decision for the neonicotinoids, and submitting data and comment on the protection of pollinators. EPA has given due consideration that the registrant has made reasonable progress toward registration.